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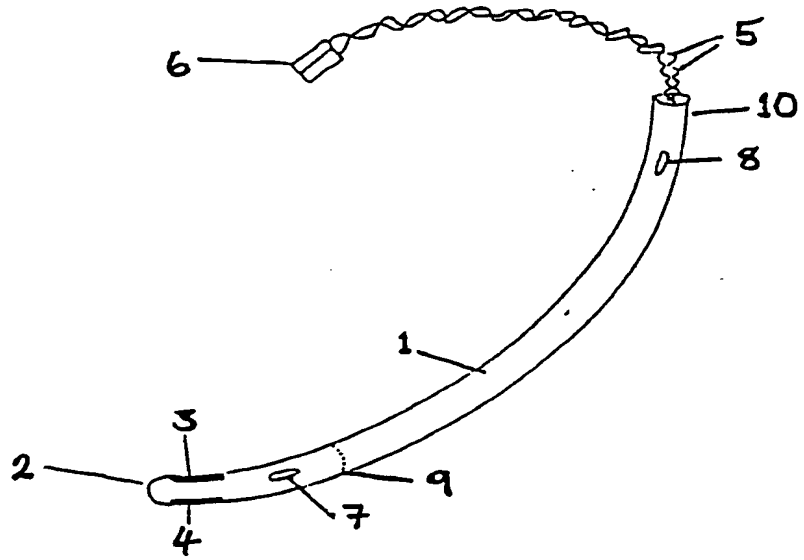

(57) Abstract

A probe for locating an endo-tracheal or endo-oesophageal tube in the trachea or oesophagus, comprises an elongate body (1) having a distal end (2) for insertion into the trachea or oesophagus of a patient, and a proximal end (10) adapted to remain external to the patient in use. A pair of electrodes (3, 4) is circumferentially spaced about the probe body, at or near the said distal end (2), and electrical conductors (5) lead between the electrodes (3, 4) and proximal end of the probe. The arrangement of the electrodes (3, 4) is such that the impedance measured between the conductors at the proximal end of the probe varies in dependance upon whether the prove is located in the oesophagus or the trachea of a patient. The probe may be a guide probe for the endo-tracheal or endo-oesophageal tube, or may itself be an endo-oesophageal tube which it is desired to insert.

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METHOD AND APPARATUS FOR LOCATING AN ENDO-TRACHEAL OR ENDO-OESOPHAGEAL TUBE IN THE TRACHEA OR OESOPHAGUS

The present invention relates to a method and apparatus for locating an endo-tracheal or endo-oesophageal tube in the trachea or oesophagus.

Endo-tracheal tubes are used during anaesthesia, resuscitation and intensive care of patients to establish a secure breathing passage from external apparatus to a patient's lungs. Endo-oesophageal tubes may be used for a variety of purposes, for example to monitor anaesthesia and blood oxygenation as disclosed in EP0050983 and EP0220180.

In general the insertion of an endo-tracheal tube is carried out with the aid of a laryngoscope. This device allows the operator to see the larynx and pass the tube through it into the trachea. It can also be used to aid insertion of an endo-oesophageal tube by enabling the operator to ensure that the tube does not pass via the larynx into the trachea, but into the oesophagus. However, in some cases the larynx may not be seen on the laryngoscope due to, for example, disease or anatomical variation. In these cases there is an increased chance of a tube being erroneously passed into the oesophagus as opposed to the trachea, or vice versa.

An endo-tracheal tube erroneously passed into the oesophagus cannot provide an adequate airway, so that the patient may become deprived of oxygen, and serious harm or death may result.

At present the preferred method of confirming the location of the tube involves pumping a quantity of air or gas (approximately 1 litre volume in an adult) through the tube into the patient, and collecting a sample of expired gas in a rapid response carbon dioxide analyser. Detection of a significant quantity of carbon dioxide in the expired gas indicates that the tube has almost certainly been passed into the trachea. The absence of carbon dioxide in the expired gas implies that the tube has been passed into the oesophagus. However, this method has the disadvantage that a sophisticated rapid response analyser must be present at the site of intubation.

It is also common practice when intubation is difficult to utilise a probe or bougie made of a flexible plastic material. Such a probe is passed along the endo-tracheal or endo-oesophageal tube prior to intubation so that it protrudes approximately 5 cm beyond the tip of the tube. The probe tip is then bent into a preferred configuration and inserted into the trachea or oesophagus ahead of the tube. The tube can then be passed down over the guiding probe.

However, it is still necessary to check that the tube has been correctly located in the trachea or oesophagus as appropriate.

According to a first aspect of the present invention there is provided a probe for locating an endo-tracheal or endo-oesophageal tube in the trachea or oesophagus which probe comprises:-

an elongate body, having a distal end for insertion into the trachea or oesophagus respectively of a patient, and a proximal end adapted to remain external to the patient in use; at least a pair of electrodes circumferentially spaced about the probe body, at or near the said distal end thereof, and respective electrical conductors connected to each of the said electrodes, and leading to the proximal end of the probe, the arrangement of the electrodes being such that the impedance measured between the conductors at the proximal end of the probe varies in dependance upon whether the probe is located in the oesophagus or the trachea.

The term "circumferentially spaced" as used herein is intended to mean that the electrodes are disposed on the probe with at least some degree of circumferential spacing (ie. they are not merely spaced along the length of the probe) so that the desired discrimination can be achieved between the oesophagus and the trachea.

The invention also provides apparatus for locating an endo-tracheal or endo-oesophageal tube in the trachea or oesophagus, which apparatus comprises:

a probe as described above, means for producing an electrical signal dependant upon the impedance between the said electrodes, and indicator means, for example a visual display or audible alarm, for producing an indication to a clinician dependant upon the impedance between the said electrodes.

In one embodiment, the probe may be a guide probe for an endo-tracheal or endo-oesophageal tube. In an alternative embodiment, the probe may be an endo-oesophageal tube which it is desired to insert.

In yet a further embodiment the probe may be an endo-tracheal tube, having a projection carrying the electrodes projecting from its distal end. In this embodiment, the projection may extend by about 5 cm from the body of the endo-tracheal tube, and conductors connected to the electrodes may pass through the endo-tracheal tube, and emerge through its wall externally of the patient.

In an adult, the trachea typically has an internal diameter of around 1.5 cm. The oesophagus is a soft walled organ which will normally collapse or contract around any tube inserted into it. The maximum diameter to which the oesophagus can safely be distended is

normally around 2cm.

Thus if the probe is a guide probe it is preferred that the probe has a diameter of from 2 to 4 mm, preferably about 3 mm. Similarly, if the probe is an endo-oesophageal tube then it is preferred that the probe has a diameter of from 3mm to 2 cm.

A preferred embodiment of the apparatus includes respective connectors connected to each of the said conductors for connecting the electrodes to a circuit responsive to the impedance between the electrodes, the connectors being adapted to remain external to the patient in use.

The electrodes are preferably elongate and arranged longitudinally on the surface of the probe.

In embodiments of the invention where there is a single pair of electrodes, the electrodes are preferably positioned substantially diametrically opposite one another. The probe may be curved, and the electrodes may be positioned one on the inner aspect of curvature and the other on the outer aspect of curvature.

Alternatively there may be provided three electrodes, in which case it is preferred that the electrodes are substantially equally spaced around a circumference of the probe.

It is preferred that the probe is provided with a

longitudinal channel for the passage of gas to enable the venting of gas from the oesophagus so that the electrodes are not located in an air pocket.

Preferably, the probe is provided with a moveable stop to prevent insertion of the probe beyond a predetermined depth.

The probe may also be provided with markings at positions along its length to indicate the depth of the probe in the trachea or oesophagus.

In a preferred embodiment, the apparatus includes a comparator circuit for comparing the impedance between the electrodes with a reference impedance.

The apparatus may also include damping means to prevent the indicator means from responding to transient changes in impedance.

The invention also including within its scope, a method for locating an endo-tracheal or endo-oesophageal tube in the trachea or oesophagus which method is carried out using a probe in accordance with the invention.

A preferred embodiment of the invention will now be described with reference to the accompanying drawings in which:-

Figure 1 shows a guide probe, and

Figure 2 shows, in schematic form, a circuit to which the probe is coupled in use.

Figure 1 shows a guide probe 1 having a distal end 2, and having two elongate electrodes 3, 4 located near the distal end 2, the electrodes being arranged so as to be substantially diametrically opposite one another.

A typical diameter of such a probe for use in adults is approximately 3 mm. In the embodiment illustrated, the electrodes 3, 4 are 10 mm in length and 2 mm in width. The main body of the probe may be made of a plastics material such as polyurethane, PVC or PTFE, and the electrodes may consist of a layer of metal or conductive plastic on the surface of the probe.

Two wires 5, connected one to each electrode 3, 4, run internally of the probe and emerge at the proximal end 10 of the probe. The wires 5 terminate in a pair of connectors 6, to enable the electrodes to be coupled to an external circuit.

A longitudinal channel is formed within the main body of the probe 1. Holes 7 and 8 in the probe communicate with the channel. The hole 7 is located near the position of the electrodes 3, 4, so that any gas trapped around the electrodes in use can escape along the channel, emerging externally of the patient via the hole 8.

A circumferential marking 9 is provided on the

probe as an indication that no lubricating gel should be placed on the probe beyond this marking.

Figure 2 is a schematic representation of a circuit for use with the probe 1. A second pair of connectors 15 is adapted to be coupled to the first pair of connectors 6 to enable an impedance measuring circuit 16 to determine the impedance between the pair of electrodes 3, 4. The measured value of this impedance is indicated on a display 17 such as a meter or a digital display.

A comparator circuit 18 compares the measured impedance with a selected reference impedance 19. The comparator output then activates a high/low detector circuit 20 which, dependant upon the level of the measured impedance, activates a lamp 21 and a buzzer 22.

In operation, the probe 1 is first introduced through, for example, an endo-tracheal tube so that the tip 2 of the probe extends approximately 5 cm beyond the end of the tube. The probe tip may then be bent into a preferred configuration for insertion into the larynx and trachea ahead of the endo-tracheal tube. Once inserted, if the probe is correctly located in the trachea, which is a rigid cartilagenous tube lined with moist mucosa, then it is likely that only one of the electrodes will be in contact with the

mucosal lining of the trachea. Thus, if the probe has been correctly located in the trachea, the impedance indicated by the display 17, corresponding to the impedance between the electrodes 3, 4, will be high. In contrast to the trachea, the oesophagus is a non-rigid muscular tube lined with mucosa which, unless distended by food or a pocket of gas, remains in a collapsed state. Thus if the probe is erroneously located in the oesophagus it is likely that both electrodes will be in contact with mucosal surfaces. In this case, the impedance between the electrodes, as indicated by the display 17, will be low.

Since a high impedance indicates that the probe is correctly located in the trachea, the reference impedance 19 may be set to an appropriate level for comparison with the output of the impedance measuring circuit 16 by the comparator 18. If the measured impedance falls below this reference value during insertion of the probe then the high/low detector 20 activates the lamp 21 and/or buzzer 22 to indicate that the probe has been erroneously passed into the oesophagus. Advantageously, the circuit of Figure 2 is provided with a damping component to prevent transient changes in impedance activating the warning device.

The longitudinal channel in the probe allows any gas trapped in the region of the electrodes during intubation to escape. This prevents the possibility of detecting a high impedance if the probe is erroneously located in the oesophagus due to distension of the oesophagus by a gas pocket in the region of the electrodes.

When correct location of the probe in the trachea is achieved, the endo-tracheal tube is passed down over the probe, and the probe is then removed.

Obviously if the probe is to be used to locate an endo-oesophageal tube, the reference impedance is set to a low value, and the high/low detector is adjusted to activate the warning device if the measured impedance increases above the reference level.

It will be appreciated that the above description relates to a preferred embodiment only, and that there are many possible variations and alternatives within the scope of the invention. For example:

1. The probe may be an endo-oesophageal tube to be inserted, as opposed to a guide probe.

2. There may be more than 2 electrodes provided on the probe, and the circuitry may be adapted to sense a high or low impedance between any pair of electrodes.

CLAIMS

1. A probe for locating an endo-tracheal or endo-oesophageal tube in the trachea or oesophagus which probe comprises:

an elongate body, having a distal end for insertion into the trachea or oesophagus respectively of a patient, and a proximal end adapted to remain external to the patient in use;

at least a pair of electrodes circumferentially spaced about the probe body, at or near the said distal end thereof, and

respective electrical conductors connected to each of the said electrodes, and leading to the proximal end of the probe, the arrangement of the electrodes being such that the impedance measured between the conductors at the proximal end of the probe varies in dependance upon whether the probe is located in the oesophagus or the trachea.

2. A probe as claimed in Claim 1 wherein the probe is a guide probe for the endo-tracheal or endo-oesophageal tube.

3. A probe as claimed in Claim 2 wherein the probe has a diameter of from 2 to 4 millimetres.

4. A probe as claimed in Claim 1 wherein the probe is an endo-oesophageal tube which it is desired to insert.

5. A probe as claimed in Claim 4 wherein the probe has a diameter of from 2 mm to 20 mm.

6. A probe as claimed in Claim 1 including respective connectors connected to each of the said conductors for connecting the electrodes to a circuit responsive to the impedance between the electrodes, the connectors being adapted to remain external to the patient in use.

7. A probe as claimed in Claim 1 wherein the electrodes are elongate and are arranged longitudinally on the surface of the probe.

8. A probe as claimed in Claim 1 including a single pair of substantially diametrically opposed electrodes.

9. A probe as claimed in Claim 8, wherein the probe is curved, the electrodes being positioned one on the inner aspect of curvature and the other on the outer aspect of curvature.

10. A probe as claimed in Claim 1 comprising three electrodes substantially equally spaced around a circumference of the probe.

11. A probe as claimed Claim 1 having a longitudinal channel for the passage of gas.

12. A probe as claimed Claim 1 including a moveable stop to prevent insertion of the probe beyond a predetermined depth.

13. Apparatus for locating an endo-tracheal or endo-oesophageal tube in the trachea or oesophagus which apparatus comprises:

a probe as claimed Claim 1,

means for producing an electrical signal dependant upon the impedance between the said electrodes, and

indicator means for producing an indication to a clinician dependant upon the impedance between the said electrodes.

14. Apparatus as claimed in Claim 13 wherein said indicator means comprises a visual display and/or audible alarm.

15. Apparatus as claimed in Claim 14 including a comparator circuit for comparing the impedance between the said electrodes with a reference impedance.

16. Apparatus as claimed Claim 15 including damping means to prevent the indicator means responding to transient changes in impedance.

17. A method for locating an endo-tracheal or endo-oesophageal tube in the trachea or oesophagus which method comprises:

inserting into the oesophagus or trachea of a patient, a probe as claimed in Claim 1,

producing an electrical signal dependant upon the impedance between the said electrodes, and

producing an indication dependant upon the impedance between the said electrodes.

FIG.1

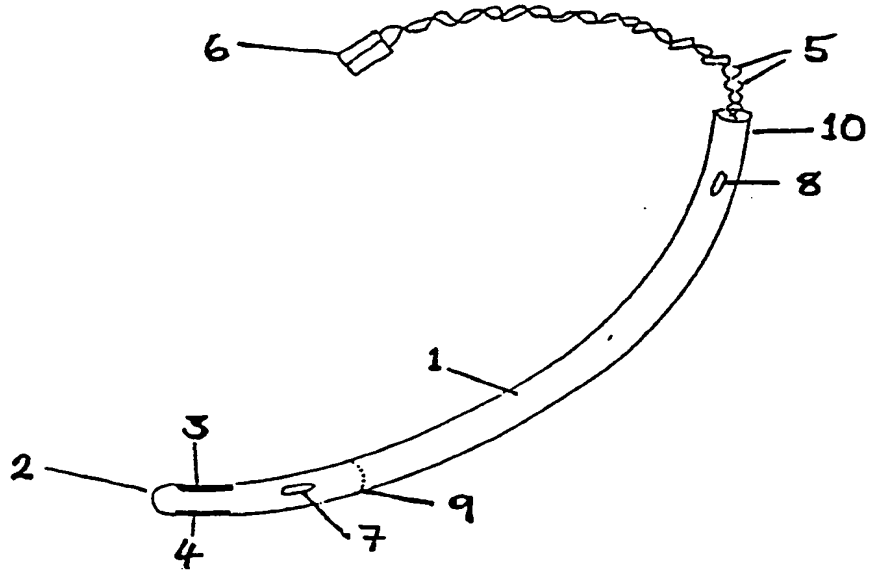
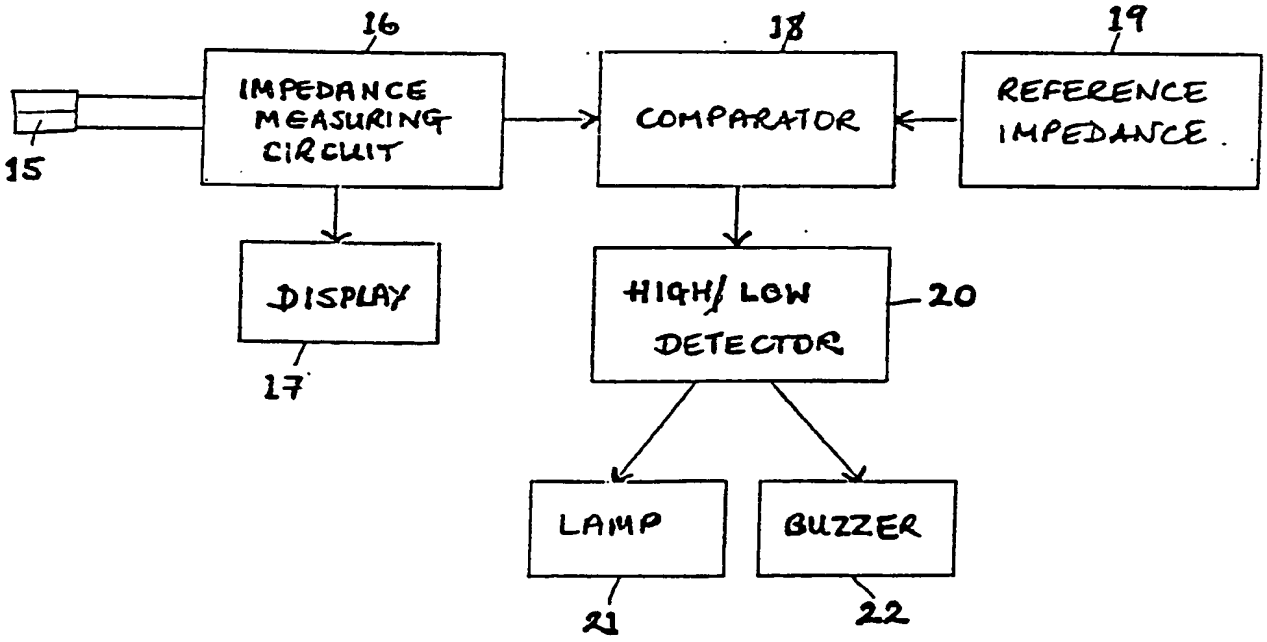

6
5
10
8
1
3
2
9
4
7

FIG.2


16
18
19
IMPEDANCE MEASURING CIRCUIT
COMPARATOR
REFERENCE IMPEDANCE
15
DISPLAY
HIGH/LOW DETECTOR
20
17
LAMP
BUZZER
21
22

INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 89/00192

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[4]: A 61 B 5/05

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[4]	A 61 B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
A	US, E, 31377 (MYLREA et al.) 13 September 1983, see figures 1-6; column 2, line 43 - column 4, line 6 --	1,2,7,8
A	US, A, 3128760 (BAKER) 14 April 1964, see figures 1,2,4; column 2, line 33 - column 3, line 46; column 4, line 21 - column 5, line 27 --	1,6,10,13, 14
A	FR, A, 667600 (DWORZAN) 18 October 1929, see figures 1-4; page 1, lines 1-39; page 2, line 12 - page 3, line 35 ----	1,2,6-8,13, 14

* Special categories of cited documents: [10]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
15th June 1989	05 JUL 1989
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	P.C.G. VAN DER PUTTEN

Form PCT/ISA/210 (second sheet) (January 1985)

See notes on accompanying sheet

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 8900192 SA 27226

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 30/06/89 The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-E- 31377	13-09-83	US-A- 4176660	04-12-79
US-A- 3128760		None	
FR-A- 667600		None	